EC DECLARATION OF CONFORMTIY

I.A.C.E.R. S.r.l

Via Enzo Ferrari 2 – 30037 Scorzè (Ve), Italia

herewith declares under its own responsibility, that the products

MIO-SONIC

UMDNS Code**: 11248**

Batch no.:

Series no.:

comply with the essential safety requirements of the European Medical Device Directive 93/42/EEC (transposed in Italy by the D.Lgs. 46/97), as modified by the Directive 2007/47/EC (D.Lgs.37/2010) and further modifications/integrations.

The product has been assigned to class IIa, according to Annex IX, rule 9 of the Directive 93/42/EEC (and further modifications/integrations) and bears the mark

CE **0068**

Compliance of the concerned product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

0068 – MTIC InterCert S.r.l.

Via G. Leopardi 14, Milano (MI) 20123, Italia

Certificate no.: **0068/QCO-DM/235-2020**

following the certification procedure according to Annex II (excluding point 4) of the Directive 93/42/EEC.

The devices comply with the following applicable standards:

EN 60601-1:2006 + A1:2013, EN 60601-1-2:2015, IEC 60601-1-6:2013, IEC 60601-2-5:2009, EN ISO 14971: 2019, ISO/TR 24971:2020, ISO 10993-1: 2009+AC:2010, ISO 10993-5: 2009, ISO 10993-10: 2010, EN 62304: 2015, EN 62366-1: 2015

It is also claimed that:

- The devices do not incorporate, as an integral part, any substance or a human blood derivate of point 10 of Annex 1 (Directive 2007/47/CE);
- no fabrics of animal origin have been used in the production as per Regulation (EU) no. 722/2012 of the Commission.

Scorzè, 31/01/2023

Place, date

MASSIMO MARCON

Legal Representative

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R.E.A.: VE N. 120250 - M. VE001767 - Codice SDI/SDI Code: SUBM70N - Cap. Soc.: € 1.000.000,00 i.v.